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Original article

Immediate- and medium-term effects of simultaneous percutaneous corrections of secundum type atrial septal defect combined with pulmonary valve stenosis in local anesthesia and without transesophageal echocardiography guidance

Xu-Dong Xu (MD, PhD)[a,1], Xue-Yan Ding (MD)[b,1], Su-Xuan Liu (MD, PhD)[a,1], Yuan Bai (MD, PhD)[a], Xian-Xian Zhao (MD, PhD)[a,**], Yong-Wen Qin (MD)[a,*]

[a] Department of Cardiology, Changhai Hospital, Second Military Medical University, Shanghai 200433, PR China
[b] Cardiovascular Therapeutic Center of the 117 Hospital of the Chinese People's Liberation Army, Hangzhou 310007, PR China

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ABSTRACT

Background: The feasibility and efficacy of simultaneous percutaneous treatment of secundum type atrial septal defect (ASD) combined with pulmonary valve stenosis (PS) have not been proved.
Objective: To evaluate the safety and efficacy on the clinical benefit of simultaneous percutaneous correction of these two pathologies under local anesthesia and without transesophageal echocardiography guidance.
Methods: Transpulmonary gradient, functional status, pulmonary regurgitation (PR), and tricuspid regurgitation (TR) were studied in 35 patients undergoing percutaneous balloon pulmonary valvuloplasty and ASD closure from March 2004 to July 2012. All patients were followed up until January 2013, an average of 39 months.
Results: According to color Doppler transthoracic echocardiography (TTE) before the intervention, the ASD defect size and transpulmonary gradient were 17 ± 8.4 mm and 88 ± 37.8 mmHg, respectively. Post-interventionally, the peak-to-peak transpulmonary gradient decreased from 77 ± 37.6 mmHg to 20 ± 16.2 mmHg ($p < 0.001$) and the ASD occluder size was 23 ± 10.5 mm. In all those patients, there was no residual shunt detected, and moderate and severe TR decreased from 45.7% (16/35) and 20% (7/35) to 8.6% (3/35) and 5.7% (2/35) before and after intervention detected by TTE, respectively. Eight patients had mild PR after procedure and two of them recovered at 6 months and no patient encountered severe adverse events at the latest follow-up.
Conclusion: Simultaneous percutaneous corrections of ASD combined with PS are feasible, safe, and effective with satisfactory results.

Introduction

Pulmonary valve stenosis (PS) and secundum type atrial septal defect (ASD) are common forms of congenital heart disease. Since the first successful clinical application and report in 1982 [1], percutaneous balloon pulmonary valvuloplasty (PBPV) has replaced surgery as the initial treatment of choice in patients of all ages with pure PS [2–5]. Nowadays, the transcatheter closure of ASDs, using various percutaneous occlusion devices in both children and adults, offers an alternative to surgical treatment due to its better clinical and follow-up results [6–9]. However, the association of PS with ASD is relatively rare, and successful transcatheter correction was reported mainly as anecdotal single case reports [10–15]. The feasibility and efficacy of simultaneous percutaneous treatment of the two pathologies have not been proved with large series of successful cases. The aim of the present study was, therefore, to evaluate the effects of simultaneous transcatheter corrections of ASD combined with PS on transvalvar

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* Corresponding author at: Department of Cardiology, Changhai Hospital, Second Military Medical University, 168 Changhai Road, Shanghai 200433, PR China. Tel.: +86 21 31161255; fax: +86 21 31161255.
** Corresponding author at: Department of Cardiology, Changhai Hospital, Second Military Medical University, 168 Changhai Road, Shanghai 200433, PR China. Tel.: +86 21 31161245; fax: +86 21 31161245.
E-mail addresses: xianxianz2010@163.com (X.-X. Zhao), qywsmmu@163.com (Y.-W. Qin).
[1] These authors contributed equally to this work.

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gradient, functional status, pulmonary regurgitation (PR), and tricuspid regurgitation (TR) at intervention in an unselected cohort of Chinese patients.

Methods

Patient population

The study population consisted of 35 consecutive patients who underwent simultaneous transcatheter ASD closure with the SHSMA occlude (Shape Memory Alloy Ltd, Shanghai, China) and PBPV with the Inoue balloon catheter (Toray Industries, Inc., Tokyo, Japan) or Cristal balloon (BALT Extrusion, Montmorency, France). Indications for ASD closure were (1) age $\geq$ 3 years; (2) 5 mm $\leq$ the maximum diameter $\leq$ 38 mm by transthoracic echocardiography (TTE), irrespective of the presence of symptoms. Our indications for PBPV were (1) the peak-to-peak catheter systolic pressure gradient across the pulmonary valve (PV) of >40 mmHg regardless of symptoms; (2) no obvious right ventricular outflow tract obstruction and pulmonary valve ring and right ventricular dysplasia.

During the study period, transcatheter combined procedure was attempted in 36 patients, but 1 patient did not undergo PBPV because of unqualified gradient detected by catheter. Transcatheter ASD closure was not attempted in patients with inadequate defect morphology or ostium primum defect detected by TTE. For these reasons, three patients referred to our institution had surgical ASD repair, pulmonary valve dissection, and tricuspid valvuloplasty during the study period. All patients underwent clinical examination, chest X-ray, electrocardiogram (ECG), and TTE before the procedure. Before intervention, informed written consent was obtained from all patients or their parents. The study was approved by the ethics committee of Changhai Hospital, and was carried out in accordance with the Declaration of Helsinki (1996) and all relevant Chinese laws.

Echocardiography

A comprehensive TTE, including M-mode, two-dimensional, and color Doppler echocardiography was routinely performed before intervention and at each follow-up visit in all patients. Transvalvar gradient was estimated from the blood flow velocity in pulmonary valve. The severity of TR was assessed on the basis of the spatial distribution of the central regurgitant jet within the right atrium by color Doppler flow mapping. TR was graded as trivial if the jet area was <1 cm^2, mild if it was <5 cm^2, moderate if it was 5–10 cm^2, and severe if it was >10 cm^2 [16]. An average of at least five determinations of each echocardiographic variable were analyzed. The quantitative and categorical data are presented as the mean $\pm$ standard deviation and as percentages, respectively.

Combined ASD closure and pulmonary valve dilatation

Wahl et al. [12] first described the procedure under local anesthesia without TEE guidance, a technique also used in the adult patients of the current report. The location, size, and relationship of ASD with the surrounding tissue (atrioventricular valve, superior and inferior vena cava, etc.) were assessed using TTE in three standard views (parasternal/cardiac apical four-chamber view, inferior xiphoid process couple atrium, and great artery minor axial views) before the procedure. The PBPV was performed first, followed by the release of ASD occluder. The femoral vein was accessed, and intravenous heparin (100 IU/kg) was administered. A multifunction catheter was introduced into the right ventricle and pulmonary artery and the maximum transvalvar gradient was obtained. A pigtail catheter was placed in the right ventricle and lateral angiograms were performed to measure the PV annulus diameters and assess the right ventricle and valve anatomy. The angiographic catheter was replaced with the multifunction catheter, which was manipulated in either the left or the right pulmonary arteries. An exchange guide wire was placed in the peripheral pulmonary artery and the multifunction catheter was replaced with the Inoue dilatation balloon or BALT balloon. The balloon was centered across the valve annulus in the lateral view and rapidly inflated by hand with diluted contrast material until the disappearance of the waist (Fig. 1 A–C). The deflated balloon was then removed while keeping the guide wire in the pulmonary artery. The guide wire permitted the repositioning of an end-hole catheter into the distal pulmonary artery for pressure measurements. Then, transcatheter ASD closure was carried out. After routine cardiac catheterization with oxymetric and pressure recordings (right ventricular and pulmonary artery pressure), a transport sheath (10–14F) was advanced over an exchange guidewire into the left atrium. The device (4–8 mm larger than the native diameter detected by TTE) was inserted into the sheath and carefully deployed. Once the selected device was implanted, and before releasing it, a new TTE evaluation in three standard views mentioned above assessed the adequacy of its position, the persistence of residual shunt, and the stability of the device within the septum. Careful pull and push movement tests of the union between the anchored device and the cannula permitted us to evaluate the possible instability of the device. After the proper size and position of the occluder was confirmed and any effect on tricuspid valve function was excluded by TTE, the occluder was completely released (Fig. 1D–F).

The following pressures were recorded before and immediately after PBPV: right ventricular systolic pressure (RVSP), right ventricular diastolic pressure (RVDP), right ventricular mean pressure (RVMP), pulmonary artery systolic pressure (PASP), pulmonary artery diastolic pressure (PADP), pulmonary artery mean pressure (PAMP), and RV to PA systolic pressure gradient.

Follow-up

Aspirin therapy (3–5 mg/kg/day) was administered for 6 months to all patients. Intravenous heparin was administered intraprocedurally. They were studied clinically and by ECG and TTE at discharge, 1, 3, 6, 12 months, and annually thereafter. Particular care was taken to determine the functional status and to obtain information regarding symptom development or any complications.

Statistical analysis

All continuous variables are expressed as mean $\pm$ standard deviation (SD) or median with range as appropriate, and discrete variables are presented as frequencies and/or percentages. We used SPSS 13.0 for Windows (SPSS, Inc., Chicago, IL, USA) for the statistical analysis. Comparisons of data were performed using the Student's *t*-test or Wilcoxon rank-sum test (continuous variables) and the chi-square test or Fisher's exact test (categorical variables) as appropriate. All tests were two-sided, and *p*-values <0.05 were considered as indicating statistical significance.

Results

Baseline characteristics

Baseline patient characteristics are shown in Table 1. Prior to intervention, 17 patients were symptomatic. Limited exercise capacity and shortness of breath were the most frequently reported symptoms. Moderate TR and severe TR were present in

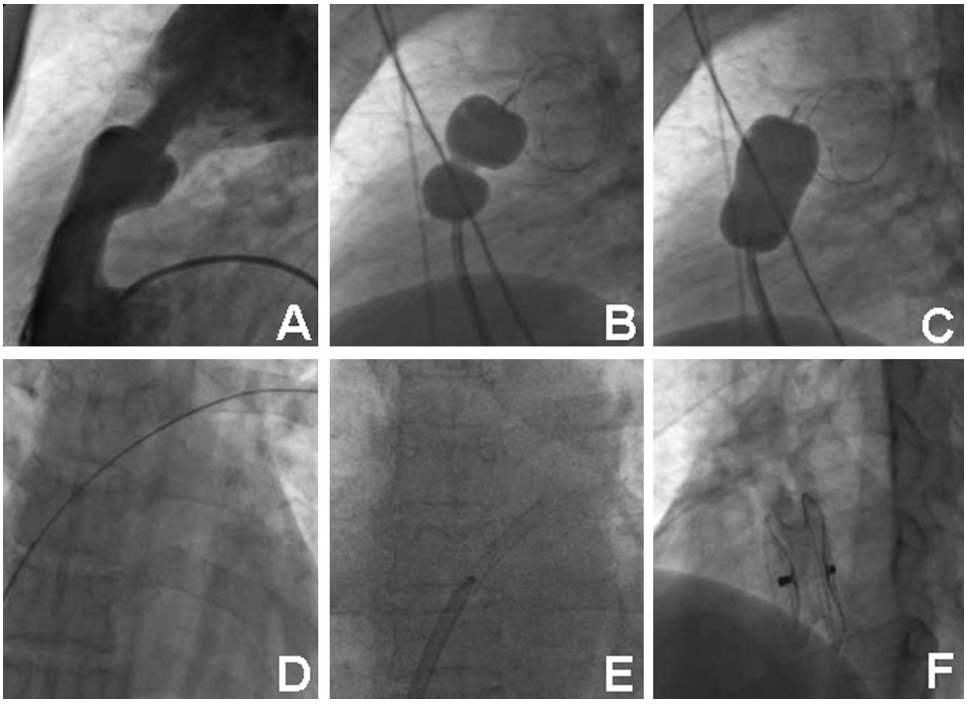

Fig. 1. Successful correction of pulmonary valve stenosis and atrial septal defect after percutaneous balloon valvuloplasty and defect occluder in a 38-year-old male patient. (A) Lateral right ventricular angiogram obtained before balloon valvuloplasty shows narrow blood jet through the severe stenotic pulmonary valve. (B) Inoue balloon (26 mm) being inflated after crossing the stenotic valve. (C) Successful inflation of the balloon with near disappearance of the waist in an adult with severe pulmonary valve stenosis. (D) The nitinol guidewire was introduced to the left superior pulmonary vein. (E) A transport sheath (10 French) was advanced over the exchange guidewire into the left atrium and the occluder was inserted into the sheath. (F) A 14-mm SHSMA atrial septal defect occluder was implanted (LAO 45° + CRAN 25°).

16 (45.7%) and 7 (20%) patients, respectively (Fig. 2). The transvalvar gradient obtained by echocardiography in the patients before anesthesia was on average 11 mmHg higher than the invasively measured pressure during local anesthesia.

Table 1
Patient characteristics at study entry (median with range).

Patients (*n*)	35
Gender (female), *n* (%)	22 (62.9)
Age (years)	32 (3–69)
Echocardiographic data	
ASD size (mm)	16 (5–38)
Transpulmonary gradient	78 (46–222)
Moderate TR, *n* (%)	16 (45.8)
Severe TR, *n* (%)	7 (20)
Clinical data	
NYHA I, *n* (%)	18
NYHA II, *n* (%)	12
NYHA III, *n* (%)	5
NYHA IV, *n* (%)	0
Catheterization	
RV systolic pressure (mmHg)	95 (67–233)
RV mean pressure (mmHg)	32 (21–105)
RV diastolic pressure (mmHg)	2 (-10–23)
PA systolic pressure (mmHg)	27 (12–43)
PA mean pressure (mmHg)	19 (7–31)
PA diastolic pressure (mmHg)	12 (4–25)
Peak-to-peak gradient	70 (40–199)
Q_p/Q_s	1.4 (0.7–2.1)
Mean size of the ASD occluders (mm)	24 (8–48)
Fluoroscopy time (min)	6 (4–12)
Procedure time (min)	43 (36–70)
Follow-up time (months)	35 (6–102)

Data are presented as mean with range where appropriate. ASD, atrial septal defect; TR, tricuspid regurgitation; NYHA, New York Heart Association functional class; Q_p:Q_s, pulmonary to systemic flow ratio; PA, pulmonary artery; RV, right ventricular.

Procedural data and complications

The transcatheter interventional procedures were successful in all patients in the present study. A total of 35 SHSMA occluders were implanted. The size of the ASD diameters ranged from 5 to 38 mm (median 16 mm), detected by TTE, and the diameters of ASD occluders ranged from 8 to 48 mm (median 24 mm). No residual shunt was detected by TTE in all patients. The peak-to-peak transvalvar gradient decreased from 77 ± 37.6 mmHg before to 20 ± 16.2 mmHg after the combined procedure (4 patients less than 12 years by BALT balloon and another 31 patients by Inoue balloon, Fig. 3, $p < 0.001$). The pulmonary valve annulus was measured from lateral view of right ventricular angiogram. The BALT balloon diameters used are 1.2 times of the pulmonary valve annulus diameter and Inoue balloon diameters are 24–26 mm. Moderate and severe TR decreased

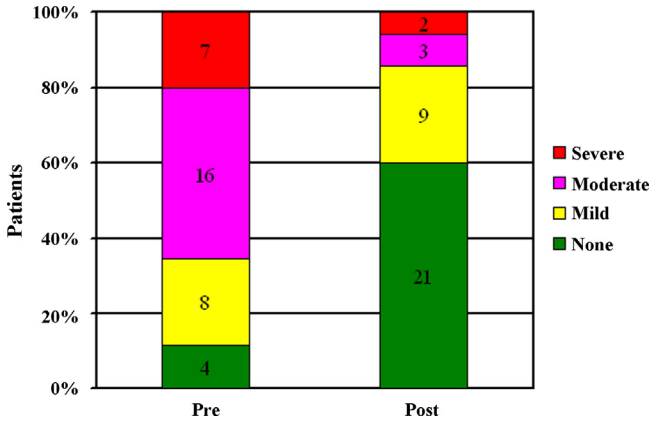

Fig. 2. Tricuspid regurgitation before (pre) and after (post) percutaneous balloon pulmonary valvuloplasty and atrial septal defect closure.

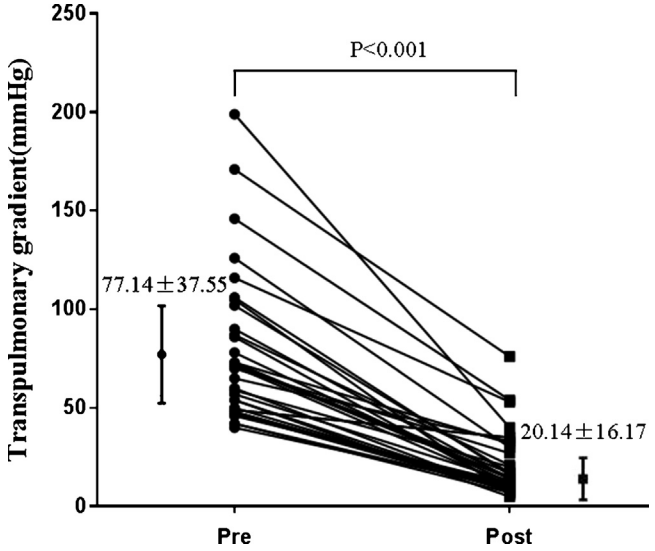

Fig. 3. The transpulmonary gradient was significantly decreased after the combined procedure.

from 45.7% (16/35) and 20% (7/35) before to 8.6% (3/35) and 5.7% (2/35) after intervention detected by TTE, respectively. Symptoms were present in 49% (17/35) of the patients before and in 17% (6/35) after the procedure. Most symptomatic patients were accompanied by significant TR, regardless of whether they were preoperative or postoperative. Eight patients had mild pulmonary regurgitation after procedure and no other major procedural complications occurred. Spontaneously resolving supraventricular arrhythmias were common during the procedure. At the end of the procedure, one patient had new atrial tachycardia and converted spontaneously to sinus rhythm. Intraprocedural pressure measurement revealed slight decreased right ventricular pressure after PBPV in two patients. They underwent successful closure without signs of right heart failure eventually. Atrial fibrillation was recorded in two patients within 24 h after the procedure. One of these spontaneously converted to sinus rhythm, whereas another underwent successful medical conversion (propafenone, 70 mg). Two patients developed transient complete right bundle branch block and recovered before discharge.

Follow-up data

The mean follow-up was 39 ± 29.9 months and early follow-up data (6 months) were available for all patients. Two patients with preexisting persistent atrial fibrillation remained in atrial fibrillation. In addition, one patient who had paroxysmal atrial fibrillation at entry developed persistent atrial fibrillation at follow-up. In all those patients having been implanted with ASD occluders, there was no residual shunt detected by TTE and all devices were in their appropriate positions. No patients had encountered serious complications, including atrioventricular conduction block, thromboembolism, erosion, and deaths during follow-up.

Regression of transvalvar gradient

Transvalvar gradient decreased from 88 ± 37.8 mmHg before to 29 ± 10.5 mmHg on day 3 and 26 ± 6.1 mmHg at 3 months and 25 ± 4.4 mmHg at 6 months after procedure ($p < 0.01$) detected by TTE.

Tricuspid regurgitation and pulmonary regurgitation

After ASD closure and PBPV, the degree of TR decreased. Only two of originally seven patients still had severe TR and three (originally 16) had moderate TR. They also improved with regard to functional status. Of the seven patients with originally severe TR, two were asymptomatic and four were in New York Heart Association (NYHA) class II and one in NYHA class III after the procedure. Interestingly, one patient with severe TR at discharge had a mild to moderate regurgitation at 1-year TTE follow-up. No patient had emerging or worsening TR. After the procedure, eight patients had mild pulmonary regurgitation detected by TTE. Two patients recovered at 6-month follow-up and another six patients remained in mild regurgitation.

Functional status

Symptomatic improvement was observed in most of the patients. After 3 months, one patient remained in NYHA class III and two patients in NYHA class II, and the other patients in NYHA class I. These three symptomatic patients were suffering from significant TR.

Discussion

PS may be valvular, infundibular, or supravalvular and is generally of the valvular type when associated with ASD. The main pathological change of this disease is obstruction of the outflow tract of the right ventricle. When the two conditions are present simultaneously, significant left-to-right shunt is often prevented by the outflow obstruction, which protects the pulmonary vascular bed without prematurely damaging until adulthood. PBPV has become the initial choice for the treatment of PS in all age groups, even neonates, given the low risk and the excellent early and late results. Therapeutic options for ASD depend on the location and size of the defect [17]. Transcatheter procedure has certain limitations, since only secundum type ASD generally less than 38 mm in diameter can be treated in this way. All small-diameter ASDs that cause no hemodynamic effects are excluded from any type of intervention, except in patients who present with paradoxical embolism, irrespective of the diameter of the ASD. However, simultaneous percutaneous treatment of the two pathologies is relatively rare. This report describes the largest hitherto published experience including mid-term follow-up of simultaneous correction of PS and ASD with special emphasis on transvalvar gradient, functional status, PR, and TR.

It is crucial to choose a correct and reasonable order to ensure the safety of transcatheter interventional therapy. But it is controversial to decide the procedure order. Treating the ASD first should eliminate the left-to-right shunt and thus also the right ventricle volumes overload and possibly lower the pressure gradient across the pulmonary valve, enabling one to reassess the severity of pulmonary stenosis. On the other hand, PBPV first lowers the peri-procedural risk of ASD occluder device dislodgement. We paid more attention to the latter and significant decline of transvalvar gradient had not been observed in most of the patients after ASD closure. Thus, the PBPV was performed first, and then the ASD closure. The indications of same period ASD closure depend on the effects of PBPV and the right ventricular compliance. Full inflation of the balloon, improvement of symptoms and cyanosis, increase of arterial oxygen saturation, decrease of right-to-left shunt and TR detected by TTE and no severe right ventricular outflow tract obstruction were suitable for the ASD closure simultaneously. In our report, simultaneous ASD closure and PBPV were performed in all patients and no one encountered serious right ventricular outflow tract spasm.

The Inoue balloon, which is shorter than other balloons, was chosen for patients who were older than 12 years, were more than 30 kg and the PV annulus was greater than 24 mm. The shorter balloon reduced the filled time and the opportunity to squeeze into right ventricular outflow tract, resulting in spasm, rise of right

ventricular pressure, and increase of right-to-left shunt. If right ventricular outflow tract was irritated, the following ASD closure should be ceased and beta-blockers should be given. About 3 months later, the ASD closure could be performed when the spasm is resolved.

Varying degrees of TR were present in almost all of these patients. Because TR cannot be repaired by an interventional approach, some cardiologists believe that these patients should be treated by surgery, including ASD repair, pulmonary valve dissection, and tricuspid valvuloplasty. But our results revealed that TR was mainly related to right ventricular volume overload attributed to increase of left-to-right and blocking of the pulmonary artery forward blood. After the combined procedure, TR reduced significantly in most of the patients, regardless of whether it was moderate or severe. These results reveal that TR is functional and will recover after transcatheter ASD closure and PBPV in most patients. Deterioration of right ventricular compliance is one of the most important reasons to reduce cardiac function reserve and activity tolerance. The cardiopulmonary bypass can reduce right ventricular compliance and maybe not the preferred approach. Moreover, transcatheter intervention can be used as a palliative means before surgery.

Ultrasound plays an important role in interventional treatment of congenital heart diseases. TTE was mainly observed in the apical four-chamber, parasternal short-axis, and subxiphoid couple atrium view in the ASD closure. The distances from anterior-inferior and posterior-superior edge of defect to the root of mitral valve anterior leaf were observed in the apical four-chamber view. The rim of atrial defect at aorta side and posterior edge were observed in parasternal short-axis view and the anteroposterior diameter of ASD can be determined. The margins next to the superior vena cava and inferior vena cava were observed in subxiphoid couple atrium view and the vertical diameter of ASD can been determined. Through these three main sections, the whole picture of ASD can be shown clearly. Our experience has shown that TTE can fully meet the need of the procedure and follow-up. The gradient had a downward trend in follow-ups, suggesting alleviation of spasm of infundibular muscle, which coincided with the report of Beghetti and colleagues [18].

Limitations

Our study demonstrated positive efficacy and safety of simultaneous percutaneous intervention of ASD and PS; nevertheless, it had some limitations. Firstly, it was a retrospective, non-randomized study in a single center in China. The experience may not be universally representative. Secondly, follow-up in our study was short and a few patients were not seen after the 6th month postoperative clinic visit.

Conclusion

Our results demonstrate that the simultaneous interventional treatment of PS and ASD is a safe and effective method. Good clinical results can be achieved as long as strict indications and contraindications were executed.

Conflicts of interest

The authors declare that there are no conflicts of interest.

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